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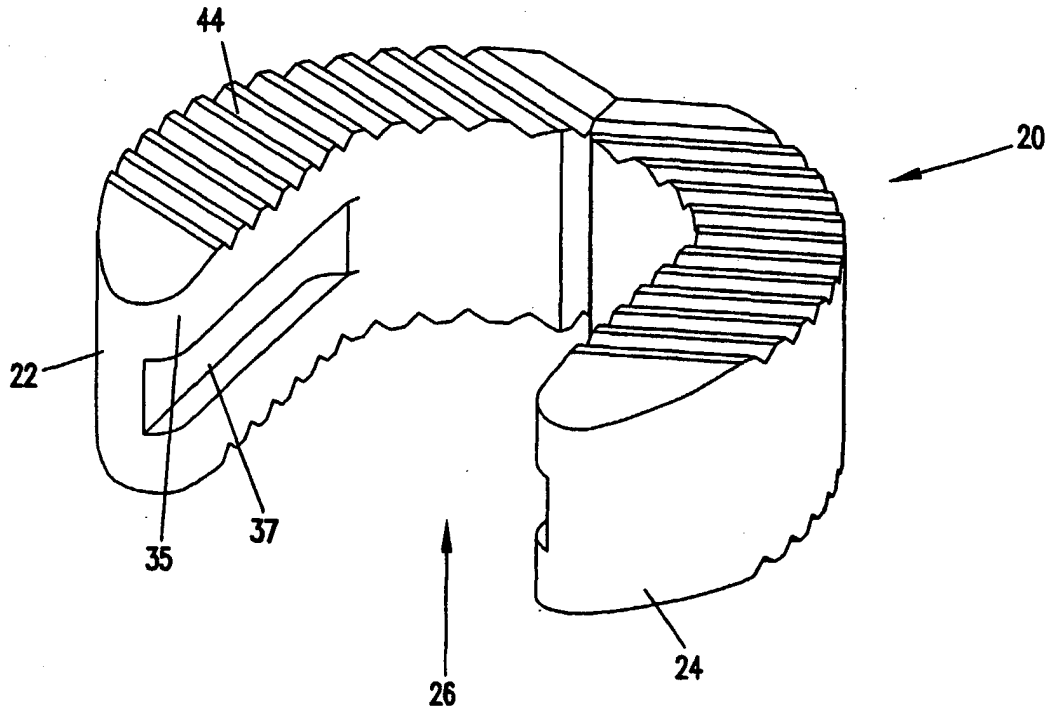
(54) Title: SKELETAL STABILIZATION IMPLANT



(57) Abstract: A spinal implant is described in this disclosure. The implant includes first and second pieces separated by a controlled break location. Spinal implant kits having multiple spinal implant pieces derived from a common source also are disclosed.

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SKELETAL STABILIZATION IMPLANT

This application is being filed as a PCT international patent application in the names of Christopher M. Banick, Jack A. Dant, David A. Hanson, and Rodney L. Houfburg, all citizens and residents of the U.S., on 27 September 2002, designating all countries.

Field of the Invention

The present invention relates generally to skeletal implants. More particularly, the present invention relates to implants for stabilizing intervertebral joints.

Background of the Invention

Chronic back problems cause pain and disability for a large segment of the population. In many cases, chronic back problems are caused by intervertebral disc disease. When an intervertebral disc is diseased, the vertebrae between which the disc is positioned may be inadequately supported, resulting in persistent pain. Stabilization and/or arthrodesis of the intervertebral joint can reduce the pain and debilitating effects associated with disc disease.

Spinal stabilization systems and procedures have been developed to stabilize diseased intervertebral joints and, in some cases, to fuse the vertebrae that are adjacent the diseased joint space. Most fusion techniques include removing some or all of the disc material from the affected joint, and stabilizing the joint by inserting an implant (e.g., a bone graft or other material to facilitate fusion of the vertebrae) in the cleaned intervertebral space.

Spinal implants can be inserted into the intervertebral space through an anterior approach, a posterior approach, or postero-lateral approach. The anterior approach involves a surgeon seeking access to the spine through the front (i.e., abdominal area) of the patient. The posterior approach involves a surgeon seeking access to the spine through the back of the patient. The postero-lateral approach is similar to the posterior approach with access coming more from either or both sides of the patient. A variety of different anterior, posterior and postero-lateral techniques are known.

It is often an advantage to use the posterior approach because such an approach typically involves a smaller and less intrusive opening than those required by anterior approach techniques. Because a posterior approach involves a smaller opening, two or more implants are often used in this approach as compared to using a single larger implant. For example, in one technique, adjacent vertebral bodies are stabilized by implanting separate implants between the vertebral bodies on opposite sides of a sagittal plane passing through the midline of the vertebral bodies. When using multiple implants to support adjacent vertebrae, it is desirable for the implants to have similar or identical mechanical properties so that uniform support is provided on both sides of the sagittal plane. In some instances, it also is desirable for the implants to have similar or identical biologic properties (e.g., to reduce the risk of tissue rejection and to enhance the uniformity of creeping substitution).

Summary of the Invention

One aspect of the present invention relates to skeletal implants and skeletal implant kits adapted to ensure that multiple implants used to support opposing vertebrae have been derived from the same source.

A variety of other aspects of the invention are set forth in part in the description that follows, and in part will be apparent from the description, or may be learned by practicing the invention. The aspects of the invention relate to individual features, as well as combinations of features. It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention as claimed.

Brief Description of the Drawings

FIG. 1 is a top, plan view of one embodiment of a spinal implant in accordance with the principles of the present invention;

FIG. 2a is a front, top perspective view of the spinal implant of FIG. 1;

FIG. 2b is a rear, perspective view of the spinal implant of FIG. 1;

FIG. 2c is a front view of the spinal implant of FIG. 1;

FIG. 2d is a side view of the spinal implant of FIG. 1;

FIG. 3 shows the spinal implant of FIG. 1 split into two pieces;

FIG. 4 shows one piece of the spinal implant of FIG. 1;

FIG. 5a is a cross-sectional view taken along section line 5a-5a of FIG. 1;

FIG. 5b is a cross-sectional view taken along section line 5b-5b of FIG. 1;

FIG. 5c is a cross-sectional view taken along section line 5c-5c of FIG. 1;

FIG. 6a-6e show various views of an insertion tool suitable for inserting the spinal implant of FIG. 1;

FIG. 7 is a kit incorporating the spinal implant of FIG. 1;

FIG. 8 is a kit incorporating the spinal implant of FIG. 1 with the spinal implant being separated into two pieces; and

FIGS. 9a and 9b show the spinal implant of FIG. 1 inserted into the intervertebral space between two vertebrae.

Detailed Description

The present invention is directed to skeletal implants, skeletal implant kits and methods for placing implants between bones desired to be fused. It is preferred for the implants to be used for vertebral/spinal applications such as fusing cervical, thoracic and/or lumbar intervertebral joints. In the case of fusing an intervertebral joint, implants in accordance with the principles of the present invention can be implanted using an anterior, posterior or postero-lateral approach to the patient's vertebrae.

As used herein, an "implant" includes any implant suitable for facilitating fusion between adjacent bones and includes implants prepared from known implant materials including, non-bone material such as titanium, stainless steel, porous titanium, bio-glass, calcium phosphate, ceramic, carbon fiber-based polymers, biodegradable and polymers. However, it is preferred for implants in accordance with the principles of the present invention to be derived from natural bone tissue (e.g., allograft and xenograft bone). It is most preferred for implants in accordance with the principles of the present invention to be derived from natural bone such as from a cadaveric allograft bone source. For example, the implants can be derived by cross-sectioning cortical rings from cadaveric allograft bones such as

femur, tibia or fibia bones. Alternatively, the implants can be formed/molded from ground, sintered or composite bone material. Bone tissue cut from a human femur bone is particularly suited for use in practicing the principles of the present invention. Xenograft bones (e.g., from a bovine source) also can be used.

The term "allograft" will be understood to mean a bone implant from a donor transplanted to a genetically dissimilar recipient of the same species. The term "xenograft" will be understood to mean a bone implant from a donor transplanted to a recipient of a different species.

FIG. 1 shows a spinal implant 20 that is an embodiment of the present invention. As shown in FIG. 1, the spinal implant 20 includes first and second pieces 22, 24 (i.e., legs). The first and second pieces 22, 24 include portions opposing one another so as to define an inner pocket 26. The first and second pieces 22, 24 are integrally connected to one another at a central connection location 28. In one embodiment, the implant member 20 has a reduced cross-sectional area at the central connection location 28. The reduced cross-sectional area provides a controlled break location at the central connection location 28. As best shown in FIGS. 5a-5c, the region of reduced cross-sectional area at the central connection location 28 is smaller than nominal cross-sectional areas (average cross-sectional areas) of each of the first and second pieces 22, 24 of the spinal implant member 20.

As shown in FIG. 1, the spinal implant 20 has a generally "C" or "U" shape. The implant member 20 includes a convex outer boundary 30 and an inner boundary 32 having a concave portion 33 and opposing straight portions 35. As shown in FIGS. 2a and 2c, grooves 37 may be cut in the straight portions 35. A fixture fits within the grooves 37 to secure the implant during manufacture of the implant 20. The inner boundary 32 defines the pocket 26 of the implant 20.

Referring again to FIG. 1, a first notch 34 located at the outer boundary 30 of the implant 20 defines the reduced cross-sectional area at the controlled break location. A second notch 36 located at the inner boundary 32 of the spinal implant 20 also defines the reduced cross-sectional area. The first notch 34 is preferably larger than the second notch 36. Both notches 34 and 36 are aligned along an axis of symmetry 38 of the spinal implant 20.

Preferably, the controlled break location is configured to allow the first and second pieces 22, 24 of the implant member 20 to be manually broken or

"snapped" apart without requiring the use of a tool. The controlled break structure ensures that the implant 20 will break at a predetermined location (e.g., at the axis of symmetry 38 for the embodiment of FIG. 1). The implant member 20 can be snapped by manually pulling the pieces 22, 24 apart by applying forces shown by arrows 25. Alternatively, the implant 20 can be snapped by manually pressing the pieces together as shown by arrows 27. Further, the implant member 20 can be broken by manually impacting the controlled break location against a relatively hard surface or edge such as the edge of a surgical instrument tray. In one embodiment, the reduced cross-sectional area provided at the controlled break location is at most 75 percent or, more preferably, about 50 percent of the nominal cross-sectional areas of each of the first and second pieces 22, 24. The controlled break locations can be defined by a variety of techniques for generating a "weaker" region at a desired location. Such weakened region can be formed by techniques such as notching, scoring, etching, cutting, mechanically perforating, laser perforating, etc. Alternatively, the controlled break location can be "weakened" by altering the mechanical properties of the implant material at the controlled break location by techniques such as radiation, demineralization or other techniques.

FIG. 3 shows the spinal implant 20 after the implant has been manually "snapped" at the controlled break location. While it is preferred for the spinal implant 20 to be manually broken, it will be appreciated that tools such as forceps, knives, scissors, saws, clamps or other devices could also be used to split the implant 20 into multiple separate pieces. Further, impact tools such as hammers, chisels or the like also could be used. If tools are desired to be used, a controlled break location may, but need not, be provided. Instead, a line or other demarcation can be used to define a predetermined break location that provides a guide for using the tool.

Although the embodiment of FIG. 1 shows the controlled break location located at the central axis of symmetry of the implant 20, it will be appreciated that other embodiments can include controlled break locations offset from the center of the implant. Further, multiple controlled break locations can be provided to allow the implant to be broken into more than two pieces. Further, in another embodiment, an entire cortical ring is provided having two oppositely

positioned break locations for allowing the implant to be snapped in half to form two separate implants.

Referring again to FIG. 1, the first notch 34 is defined by first and second insertion force application surfaces 40, 42 aligned at an oblique angle relative to one another. The insertion force application surfaces 40, 42 are preferably aligned parallel to grooves 44 formed in top and bottom surfaces of the spinal implant 20. During implantation of the first and second pieces 22, 24, pins of an insertion tool (e.g., see insertion tool 52 of FIGS. 6a-6e) are placed in openings 45 (shown in FIGS. 2b and 6e) defined in the insertion force application surfaces 40, 42. During insertion, insertion forces are applied to the surfaces 40, 42 via the tool 52 to individually push the pieces 22, 24 into the intervertebral space. Particularly for posterior approach techniques, it is desirable for the pieces 22, 24 to be inserted in a direction requiring the smallest possible opening to be defined through the patient's posterior region. For example, arrow 46 of FIG. 4 shows a preferred direction of insertion. It is preferred for the insertion force surfaces 40, 42 to be perpendicularly aligned relative to the preferred insertion directions of their corresponding pieces 22, 24.

The grooves 44 of the implant 20 function to resist migration of the implant upon implantation between opposing bone surfaces. Other structures such as teeth, serrations, cross-cut serrations, notches, bumps, ridges, projections or other surface treatments could also be used.

While the implant 20 can have a constant thickness, it is preferred for the implant 20 to be slightly tapered. In one embodiment, the spinal implant 20 can be tapered about 3 degrees such that a front end 48 of the implant 20 has a thickness T_f that is greater than a thickness T_r located at a rear end 50 of the implant 20. The thicknesses T_f and T_r are labeled in FIG. 2d. In another embodiment, the front end 48 of the implant 20 may be chamfered to facilitate insertion.

FIGS. 6a-6e show an insertion tool 52 suitable for individually implanting the first and second pieces 22, 24 of the spinal implant 20 into the intervertebral space of a patient. The insertion tool 52 includes an insertion end 55 having two parallel pins 57 adapted to fit within the openings 45 defined by the force application surfaces 40, 42 of the implant pieces 22, 24. The tool 52 also includes a curved retaining surface 59 adapted to contact and complement a portion

of the outer boundary 30 of the implant piece 22, 24 when the implant piece 22, 24 is mounted at the insertion end 55.

While other materials could be used, the spinal implant 20 is preferably derived from an allograft bone. In one embodiment, the implant 20 is a transverse cross-section from the femur of a cadaver, and includes a cortical ring. After the ring has been cross-sectioned, relatively soft bone tissue and marrow from the interior of the ring is preferably removed. Next, a portion of the outer cortical ring is removed (e.g., by a technique such as mechanically cutting with a blade or abrasion tool, laser cutting, etching, etc.) to provide the open end of the pocket 26 of the "C" shaped implant 20 (see Fig. 1). Bone removal techniques are then also used to shape the outer and inner boundaries 30, 32 and to form the notches 34, 36. While the particular shape depicted in FIG. 1 is preferred, it will be appreciated that other shapes also could be used without departing from the principles of the present invention.

FIG. 7 illustrates a kit 60 that is an embodiment of the present invention. The kit includes the spinal implant 20, the insertion tool 52 and instructions of use. The components are contained within a sterile package 66 (e.g., a bag, plastic container or other sealed holding configuration). In other embodiments, the kit includes the spinal implant 20, alone, within the sterile package.

FIG. 8 shows another kit 60' that is an embodiment of the present invention. Similar to the embodiment of FIG. 7, the kit 60' includes the spinal implant 20, the insertion tool 52 and the instructions of use 64. Also similar to the embodiment of FIG. 7, the various parts are held within a sterile package 66. However, in the embodiment of FIG. 8, the spinal implant 20 has been pre-broken into the first and second pieces 22, 24. Preferably, both the first and second pieces 22, 24 were derived from the same source. For example, preferably the first and second pieces 22, 24 were provided from human bone tissue from the same cadaver. More preferably, the pieces 22, 24 were provided from the same cortical ring of the same bone. By packaging two or more implant pieces from the same source in one package, the surgeon that ultimately uses the implants will be assured that the pieces will exhibit similar or identical mechanical and biological properties. Further, by using bone pieces from the same donor, the risk of transferring disease to the patient

is reduced by 50 percent as compared to using bone samples from two different donors. In other embodiments, the kit 60' includes the first and second pieces 22, 24, alone, within the sterile package.

The configuration of the implant of FIG. 1 provides similar advantages. For example, because the first and second implant pieces 22, 24 can be provided to a surgeon in an integrally connected configuration, the surgeon can be assured that the two pieces were derived from the same bone source. Further, the configuration of the controlled break location allows the surgeon to quickly and easily separate the two pieces without requiring a tool. In the event the implant is made of a non-bone material, the configuration ensures the surgeon that the implant pieces 22, 24 were manufactured in the same lot.

To implant the spinal implant 20, a diseased disc between two adjacent vertebrae 72, 74 is preferably removed using a conventional discectomy procedure (i.e., partial or complete discectomy). Opposing end plates 72' and 74' of the vertebrae 72, 74 are then preferably prepared to provide relatively flat contact surfaces. The end plates 72', 74' are then conditioned (e.g., with a rasp) to provide a more uniform and osteoconductive/osteoinductive site for the implant 20. After the implant site has been prepared, the sterile package of the kit 60 is opened, allowing the surgeon to access the implant 20. Preferably, the implant 20 is then manually "snapped" or broken into two pieces. One of the pieces 22 is then placed on the insertion tool 52. With the insertion tool, the surgeon inserts the first piece 22 into the cleared intervertebral space between the vertebrae 72, 74. Preferably, the first piece 22 is inserted using a posterior approach. As the first piece 22 is inserted, an insertion force is transferred through the insertion tool 52 to the insertion force surface 40 of the first implant piece 22. As shown in FIGS. 9a and 9b, the first implant piece 22 is preferably positioned on one side of a sagittal plane 80 that passes through the midline of the vertebrae 72, 74. Once the first implant piece 22 has been inserted, the tool 52 is withdrawn from the implant piece 22 and the second implant piece 24 is preferably inserted using the same procedure. However, the second implant piece 24 is preferably positioned on the opposite side of the sagittal plane 80. As mounted in the intervertebral space, the front end 48 of the implant 20 is preferably located at an anterior position relative to the rear end 50. To further promote fusion, additional bone material (e.g., cancellous allograft or autograft

material) or other osteoconductive/osteoinductive material can be placed in the intervertebral space corresponding to the inner pocket 26 of the implant 20. This material can be placed in the intevertebral space before insertion of the first implant piece 22, after insertion of the first implant piece 22, but before insertion of the second piece 24, and/or after both implant pieces 22, 24 have been implanted.

It will be appreciated that the kit 60' can be used in essentially the same manner as the kit 60, except the kit 60' does not require the surgeon to manually break the spinal implant 20 into the separate first and second pieces 22, 24. In both embodiments, the surgeon can be assured that both the first and second pieces 22, 24 of the spinal implant 20 were derived from the same donor source.

With regard to the foregoing description, it is to be understood that changes may be made in detail without departing from the scope of the present invention. It is intended that the specification and depicted aspects of the invention may be considered exemplary, only, with a true scope and spirit of the invention being indicated by the broad meaning of the following claims.

WE CLAIM:

1. A skeletal implant comprising:

an implant member including a predefined break location.

2. The implant of claim 1, wherein the implant member is a spinal implant member.

3. The implant of claim 1, wherein the implant member includes bone tissue.

4. The implant of claim 3, wherein the implant member is from an allograft bone source.

5. The implant of claim 1, wherein the predefined break location is configured to allow the implant member to be manually broken into separate pieces without the use of a tool.

6. The implant of claim 1, wherein the predefined break location comprises a notch located between first and second portions of the implant member, and wherein the predefined break location has a reduced cross-sectional area as compared to nominal cross-sectional areas of the first and second portions of the implant member.

7. The implant of claim 6, wherein the reduced cross-sectional area is at most about 75 percent of the nominal cross-sectional areas of each of the first and second portions.

8. The implant of claim 1, wherein the predefined break location comprises a notch defined in the implant member.

9. The implant of claim 6, wherein the first and second portions each include an insertion force application surface, the insertion force application surface of the first portion being aligned generally perpendicular to an intended line of insertion of the

first portion, and the insertion force application surface of the second portion being aligned generally perpendicular to an intended line of insertion of the second portion.

10. The implant of claim 9, wherein the insertion force application surfaces of the first and second portions are configured to define the notch of the implant.

11. The implant of claim 1, wherein the predefined break location is provided at an axis of symmetry of the implant member.

12. The implant of claim 3, wherein the bone tissue is from a femur bone.

13. The implant of claim 6, wherein the implant member includes a convex outer boundary and a concave inner boundary, and wherein the reduced cross-sectional area includes a first notch at the outer boundary.

14. The implant of claim 13, wherein the reduced cross-sectional area includes a second notch at the inner boundary.

15. The implant of claim 14, wherein the first notch is larger than the second notch.

16. The implant of claim 15, wherein the controlled break location is provided at an axis of symmetry of the implant member.

17. The implant of claim 1, wherein the implant member is generally "C" shaped.

18. A method of manufacturing a skeletal implant, the method comprising:

isolating a segment of bone; and

forming a controlled break location in the segment of bone.

19. The method of claim 18, wherein the bone is from an allograft bone source.

20. The method of claim 18, wherein the controlled break location is formed by forming a notch in the segment of bone.

21. The method of claim 20, wherein the segment of bone has an axis of symmetry separating first and second portions, wherein a first notch is formed in an outer surface of the segment and a second notch is formed in an inner surface of the segment, the first and second notches being aligned along the axis of symmetry.

22. A skeletal implant kit comprising:

a first implant portion derived from a bone source;

a second implant portion derived from the same bone source as the first implant portion; and

a package containing the first and second implant portions.

23. The skeletal implant kit of claim 22, wherein the first and second implant portions are provided as separate pieces.

24. The skeletal implant kit of claim 22, wherein the first and second implant portions are connected at a predefined break location, forming a unitary implant.

25. The skeletal implant kit of claim 24, wherein the unitary implant is manually breakable.

26. The implant kit of any of claims 22-25, wherein the bone source is a cadaveric femur bone.

27. The implant kit of any of claims 22-25, wherein the first and second implant portions are substantially the same size and shape.

FIG. 1

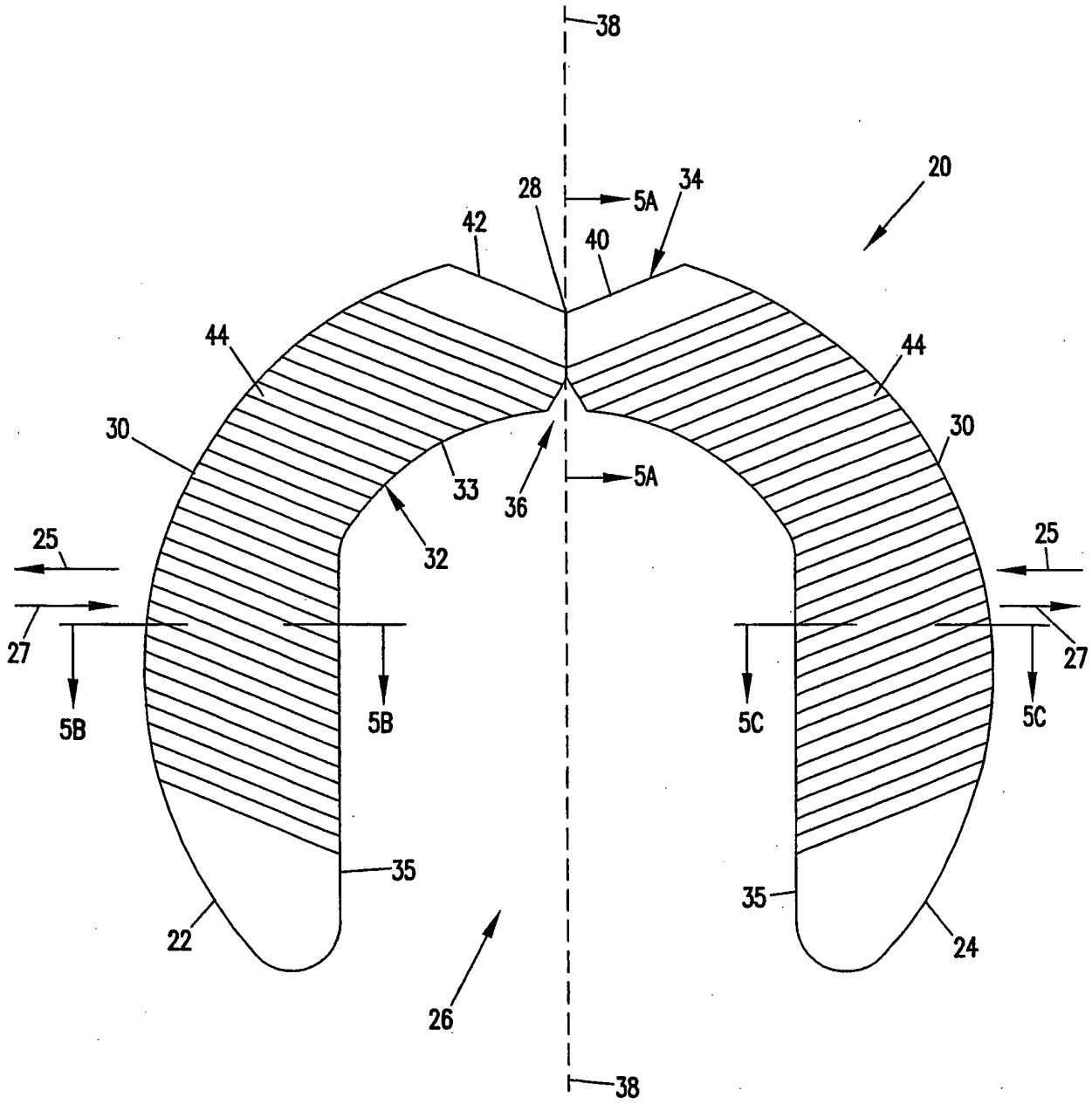
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FIG. 2A

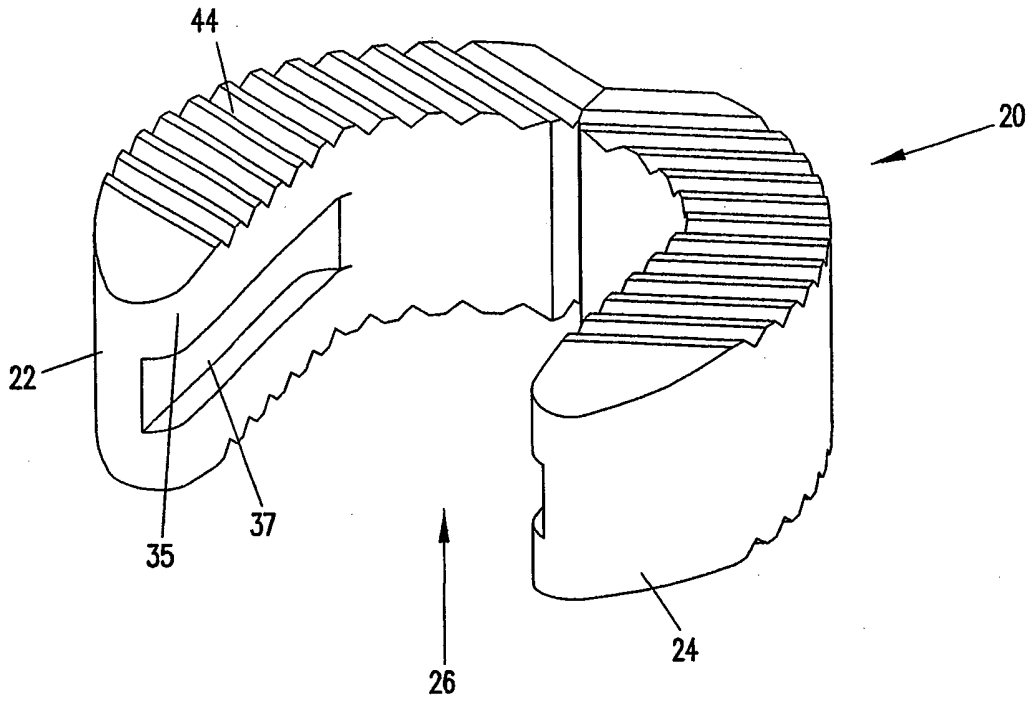


FIG. 2B

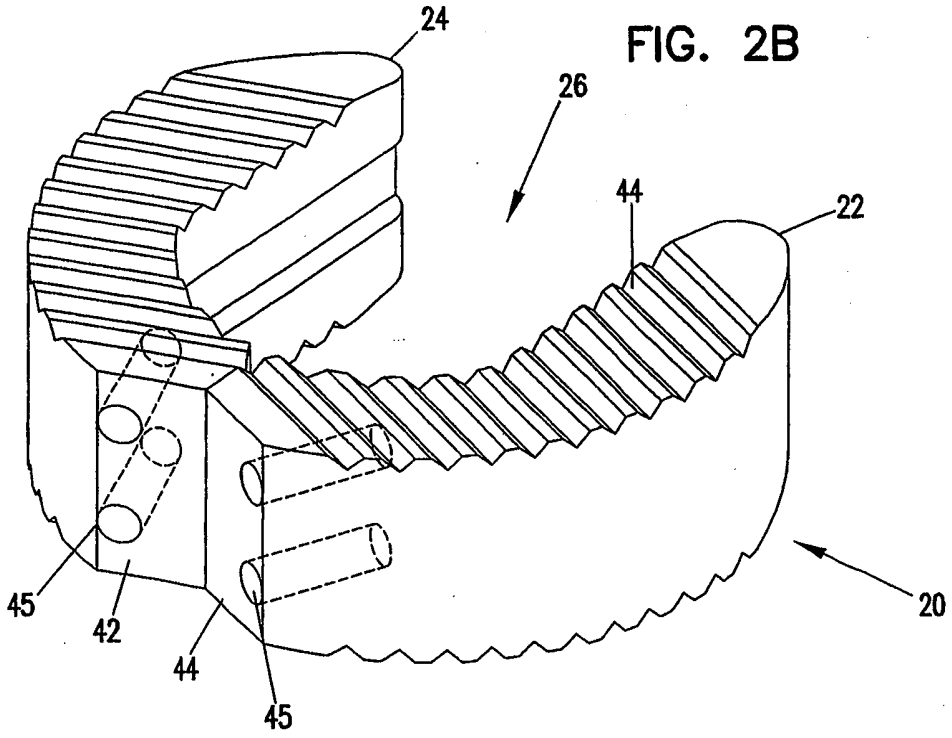


FIG. 2D

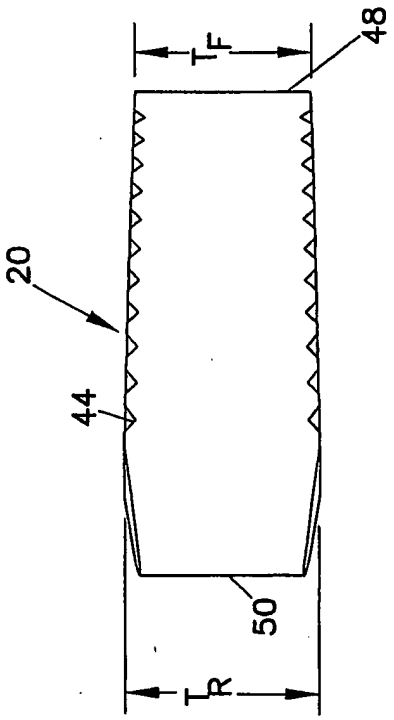


FIG. 2C

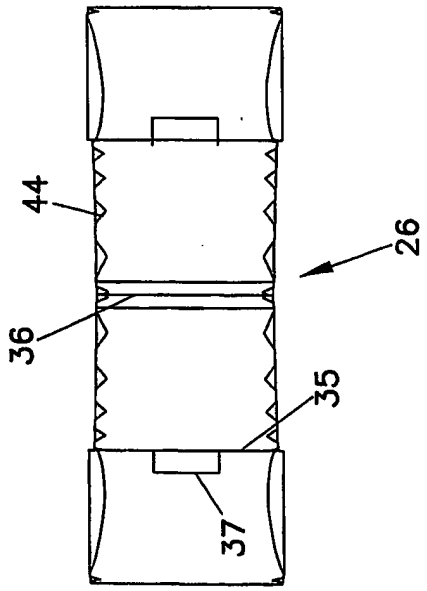
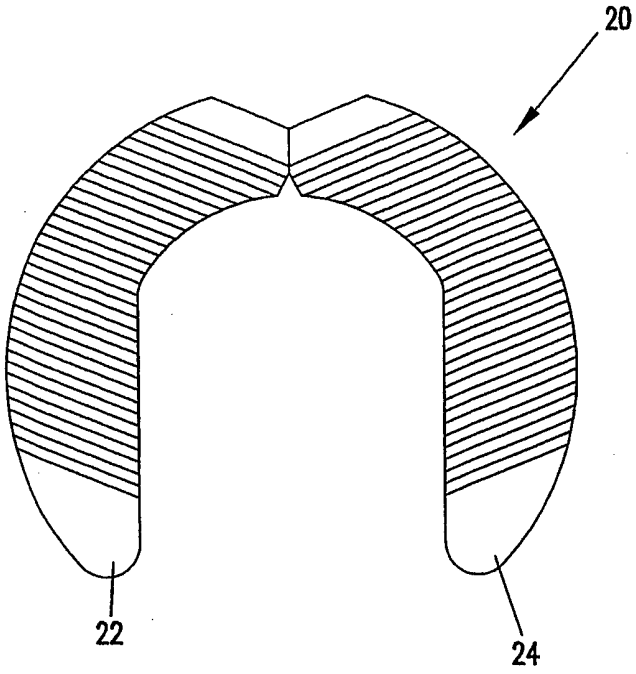


FIG. 3



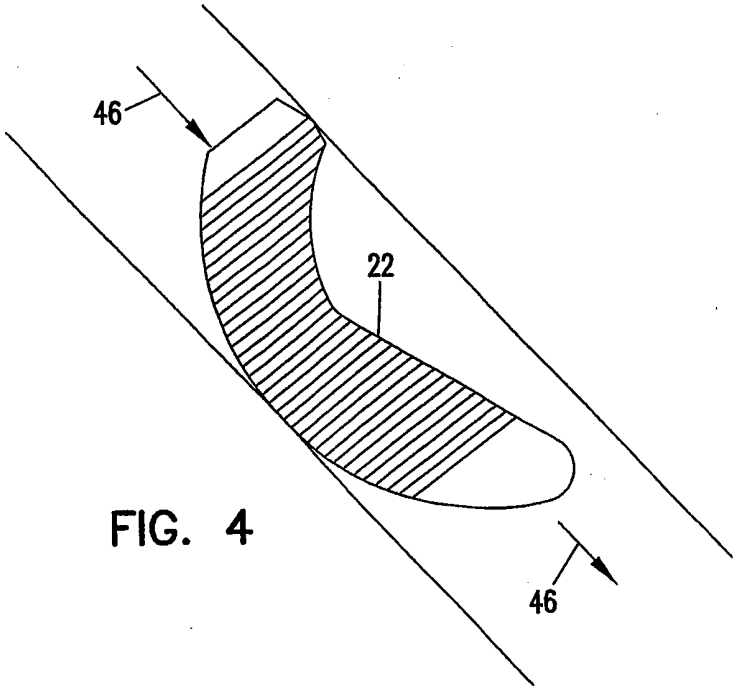


FIG. 4

FIG. 5A

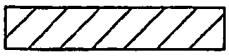


FIG. 5B

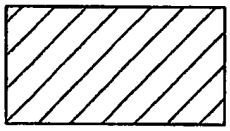
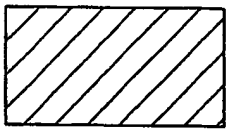


FIG. 5C



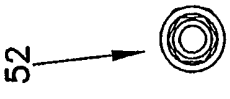


FIG. 6D

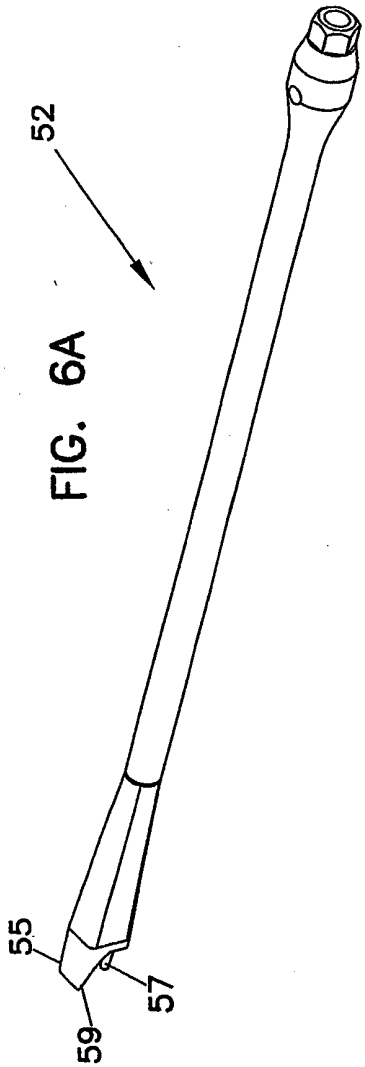


FIG. 6A

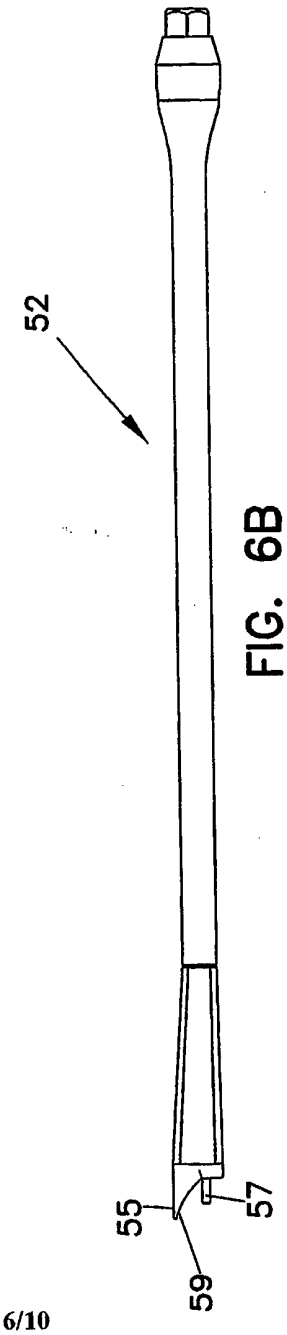


FIG. 6B

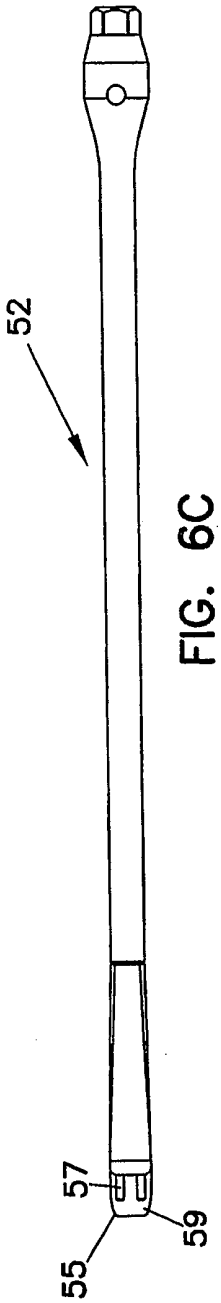
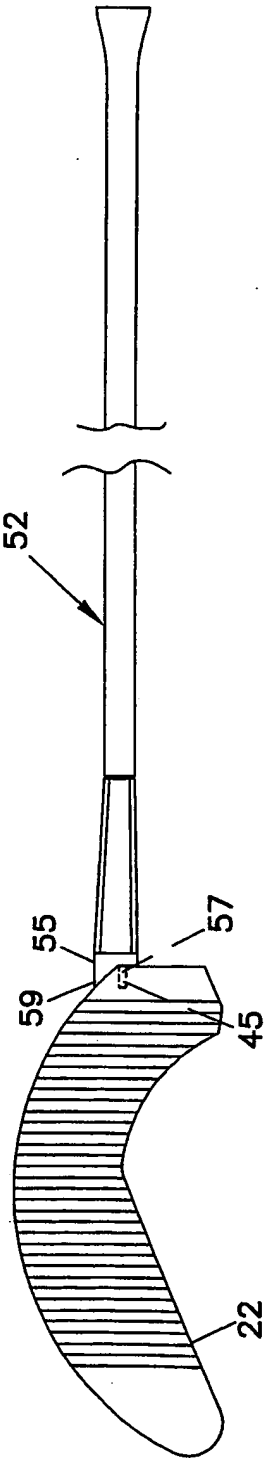


FIG. 6C

FIG. 6E



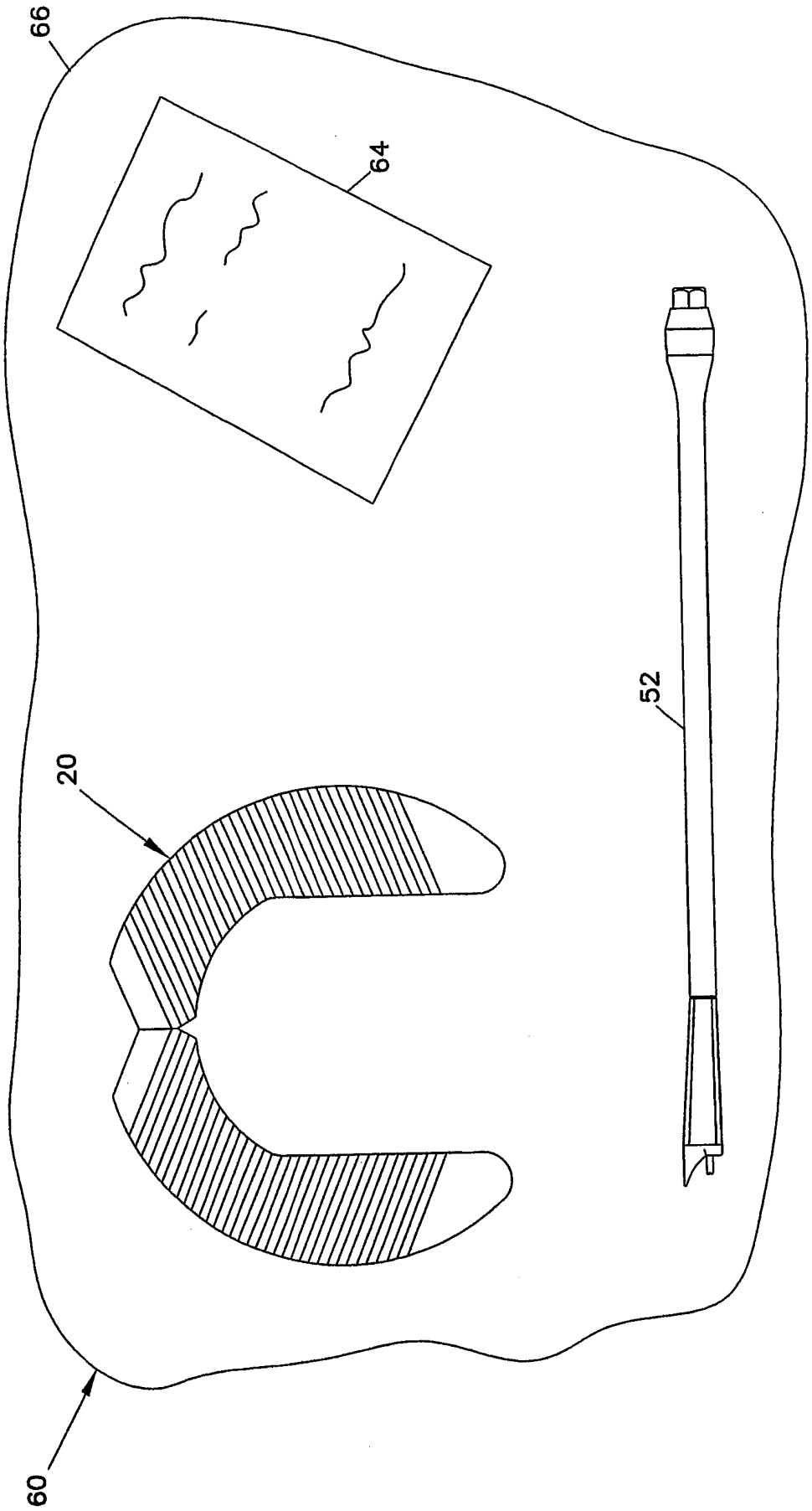


FIG. 7

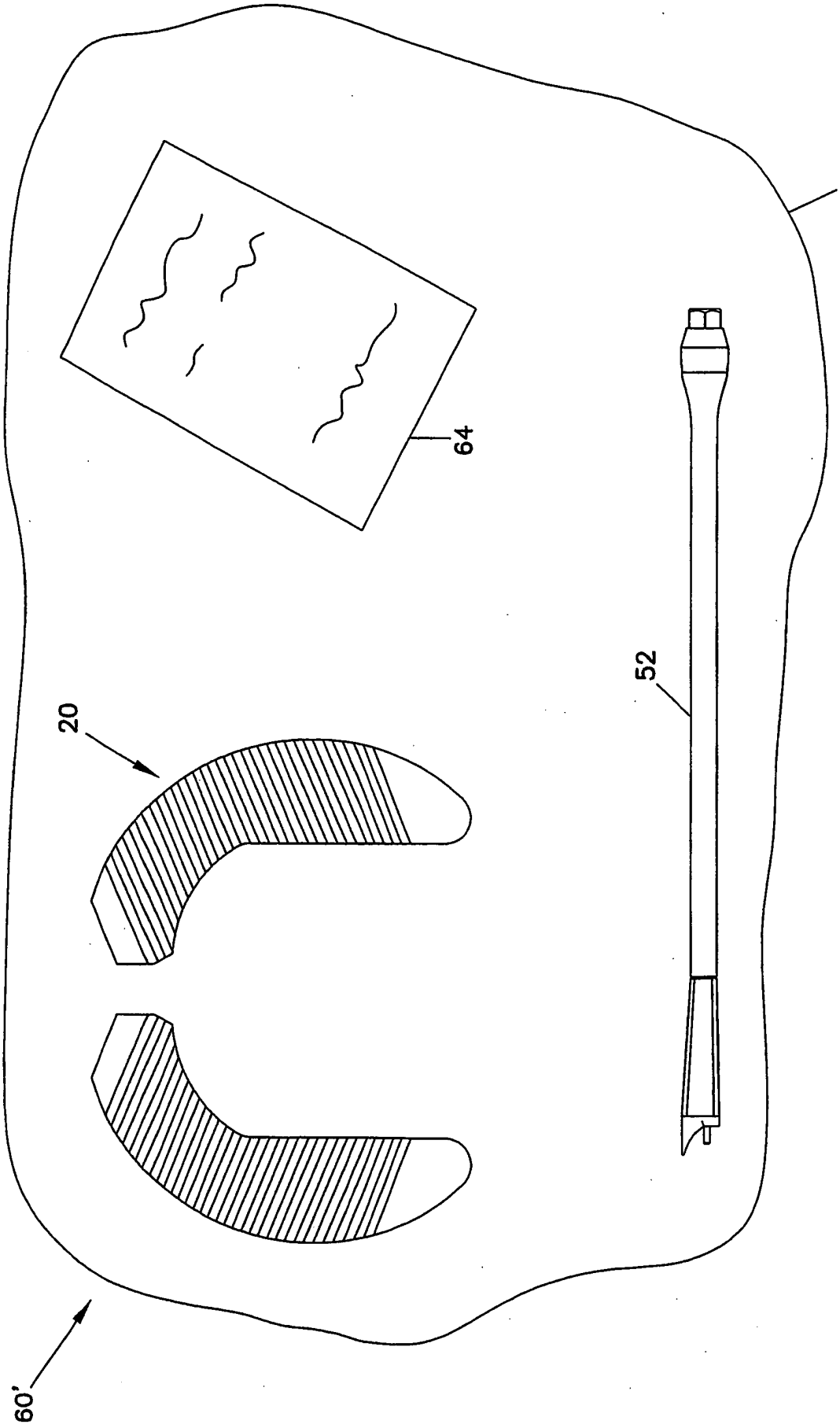


FIG. 8

FIG. 9A

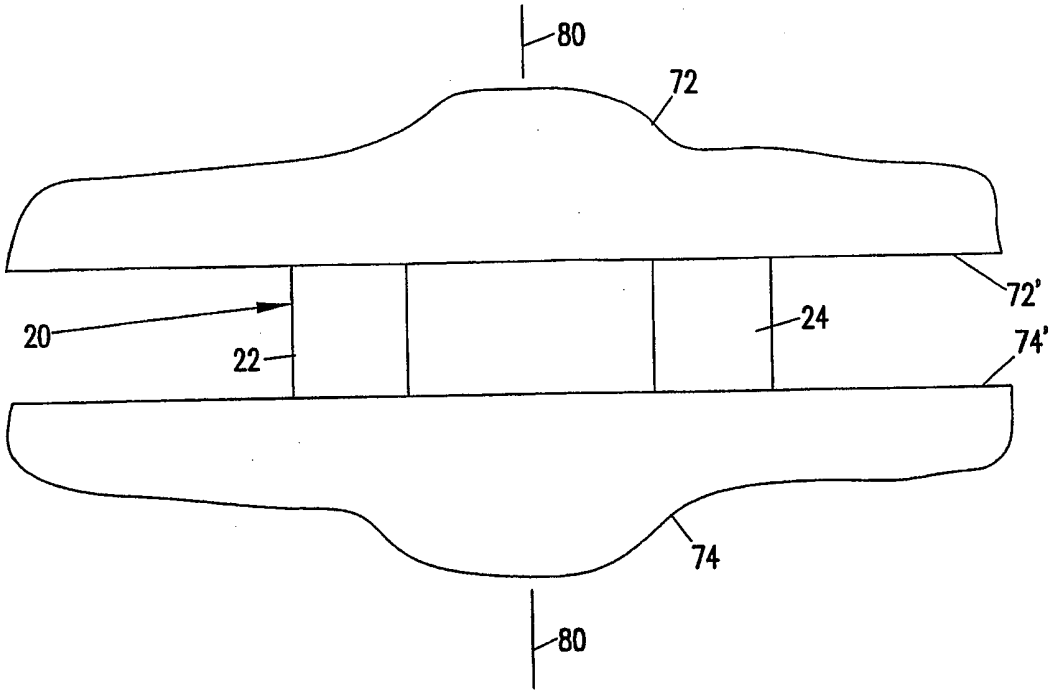
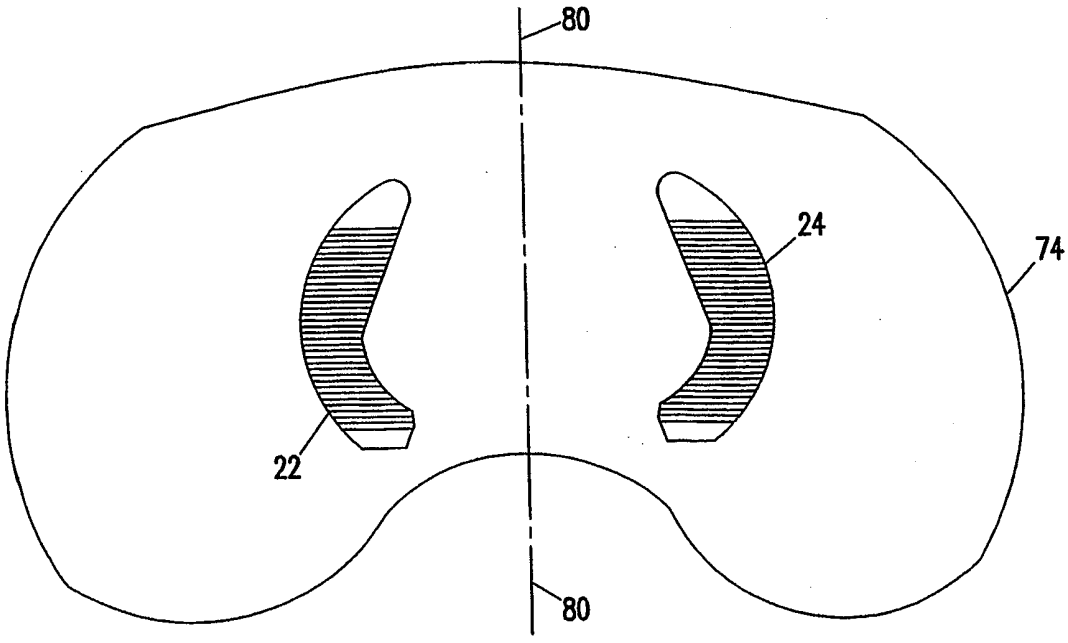


FIG. 9B



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(74) Agent: **PARSONS, Nancy, J.**; Merchant & Gould P.C., P.O. Box 2903, Minneapolis, MN 55402-0903 (US).

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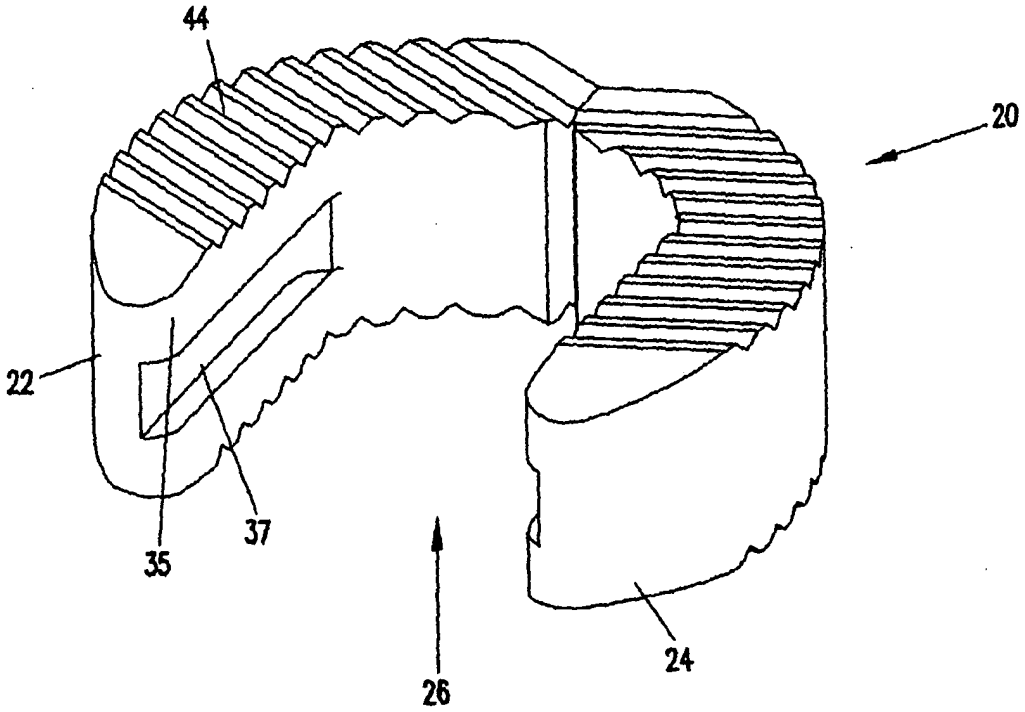
(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

[Continued on next page]

(54) Title: SKELETAL STABILIZATION IMPLANT



(57) Abstract: A spinal implant is described in this disclosure. The implant includes first and second pieces separated by a controlled break location. Spinal implant kits having multiple spinal implant pieces derived from a common source also are disclosed.

WO 03/026522 A3

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(88) Date of publication of the international search report:
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44 A61F2/28 A61F2/46

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 015 817 A (KRANZ CURT) 14 May 1991 (1991-05-14) claims 1,9; figures	1,5-8, 11,13
A	---	18
X	DE 200 17 962 U (AESCULAP AG & CO KG) 4 January 2001 (2001-01-04) claims 1,17; figures 1,6,7	1,2
A	---	18
X	EP 0 366 945 A (HERMANN AG W) 9 May 1990 (1990-05-09) claims 1,12; figures 1A,5	1,5
A	---	
	US 6 174 311 B1 (LIU MINGYAN ET AL) 16 January 2001 (2001-01-16) figures 11A,22,46A column 14, line 3 - line 7	2-4, 17-19

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
16 January 2003	06. 05. 2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Stach, R

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 00 41654 A (SDGI HOLDINGS INC ;BOYD LAWRENCE M (US); DORCHAK JOHN D (US); BURK) 20 July 2000 (2000-07-20) claim 4; figure 4 page 9, line 16 - line 17 -----	2-4, 17-19

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 02/31011

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-21

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-21

A skeletal implant comprising:
an implant member including a predefined breaking point.

(Problem: Allowing easy reduction of the size of the implant during a surgery)

2. Claims: 22-27

A skeletal implant kit comprising:
a first implant portion derived from bone source;
a second implant portion derived from the same bone source as the first implant portion; and
a package containing the implant portions.

(Problem: Keeping an implant clean during the time between production and implantation)

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